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Baseline demographics are represented in table 2. 213 participants were randomized into control group (n= 105) and intervention group (n=108). Socio-demographic characteristics at baseline are similar between two groups (Chi square test). In the control group of participants, mean age of 58.68 years with a standard deviation 10.41, median age of 60 years (range 29 to 79), belong to rural area of residence (74.3%), male being the predominant (80%) feature. Self payment (45.7%) was the major payment mode followed by Arogya suraksha (14.3%) and Sampoorna suraksha (13.3%) insurance scheme. Less than 10 years of education (60%) was the prominent feature of participants. Skilled labor (21.9%) was the major occupation followed by Home maker and Retired persons (19%). In the intervention group of participants, mean age of 56.69 years with a standard deviation of 9.46, median age of 57 years (range 24 to 77), belong to rural area of residence (66.7%), male being the predominant (80.6%) feature. Self payment (40.7%) was the major payment mode followed by Sampoorna Suraksha (14.8%) and Arogya suraksha (10.2%) insurance schemes. Less than 10 years of education (55.6%) was the prominent feature of participants. Skilled labor (24.1%) was the major occupation followed by Home maker (19.4%) and Agriculture (16.7%).

Clinical variables at baseline are represented in table no. 3. Anterior wall myocardial infarction (37.1%) and Inferior wall myocardial infarction (37%) were the major type of infarctions in control group and intervention group respectively. Single vessel (51.4% and 50.9%) as diseased vessel and LAD is the major culprit vessel (47.6% and 34.3%) in both the groups. Drug eluting stents were primarily used in the PCI procedure in both the groups (88.6% & 84.3%).

Risk factor variables are represented in table 4. Hypertension and Diabetes were the major co- morbid conditions in both the groups. Stressful life (48.6%), sedentary life
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style (43.8%), family history of cardiovascular diseases (39%), smoking and alcohol intake (30.5%) were the major risk factors in the control group. Stressful life (67.6%), sedentary life style (53.7%), family history (52.8%), and obesity (40.7%) were the major risk factors in the intervention group.

Discharge medications at baseline (table 5) are almost common for both the group of patients. Aspirin, Clopidogrel, atorvastatin (100%) were the major drugs followed by pantaprazole (98.1% & 97%). In the anti hypertensive medications, ACE inhibitors – Ramipril was prescribed (55% and 49.1%) followed by betablocker – metaprolol (37.1% & 41.7% respectively). Oral hypoglycemic drugs- Glimepride (22.9% & 37%) followed by Metformin (14.3% and 34.3%) were prescribed in both the groups. Nitrates was the another class of drugs which were prescribed (44.8% and 40.7%).

6.1 Global scores of MacNew

Global Scores of MacNew questionnaire were calculated at different time intervals by repeated measures ANOVA method and tabulated at table 7. At baseline, both the groups have similar scores (3.03 ± 1.29 & 2.89 ±1.12). Changes were observed during 9 months follow up was 2.58 ± 1.14 and 5.54 ± 1.42 for control and intervention group respectively. At the end of the study period (12 months), global score was 2.32 ± 0.91 and 5.47 ± 1.45 for control and intervention group respectively (p<0.001). The changes of global score across the study period are depicted in the figure 12.

6.2 Visual analog scale of EQ 5D 5L

EQ visual Analog Scale score at different time intervals were calculated by repeated measures ANOVA and represented in table 8. At baseline, the VAS score was 59.97 ± 14.51 and 61.01 ± 13.3 for control and intervention group respectively. At the end of the study period (12 months), scores of 73.38 ± 5.19 and 85.13 ± 4.62 recorded for control
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and intervention group respectively (p<0.001). The changes of VAS score across the study period are depicted in the figure 13.

6.3 Utility values of EQ 5D 5L

EQ Utility values were calculated by repeated measures ANOVA method and represented in Table no.9. The Utility values at baseline were similar (0.46 ± 0.17 and 0.47 ± 0.16). At 3rd follow up, 0.139 ± 0.25 and 0.72 ± 0.19 were observed for both control and intervention group respectively. At the end of the study period, the values had been decreased slightly to 0.11 ± 0.20 and 0.68 ± 0.23 for control and intervention group (Since sphericity is not assumed, GH- Geisser F value is 115.32, p<0.001) respectively. These results had been plotted in figure 14.

We calculated the relationship between utility value of EQ 5D 5L and global score of MacNew questionnaires at different time intervals and compared between control and intervention groups (Table No.10 and 11). We used the paired t test along with 95% confidence interval to detect the changes, which reveals that, there is a significant relationship between utility values of EQ5D and MacNew questionnaires at different time intervals and also between the control and intervention groups (p<0.001).

MacNew questionnaire has three different domains viz., Emotional, Physical and Social. The scores were calculated and interpreted for these domains and tabulated in table no. 12. At baseline, the scores of these domains were similar across the groups. Scores in the intervention groups were improved in all the domains at different time intervals. The data had been plotted in figure no. 15.

EQ 5D 5L, as the name suggests; has five domains and five levels viz., Mobility, Self care, Usual activity, Pain and Anxiety with five levels of discomfort. These levels were dichotomized into Problems and No problems category by grouping level 1 and level 2 into No Problem category and level 3 to 5 into Problem category. These dichotomized
levels were compared between control and intervention groups at different time intervals across the study period. This data is tabulated at table no. 13 and depicted at figure no. 16. At baseline, there was no significant variation between the groups and domains. At the first follow up, the HRQoL has improved in both the groups, especially in pain and self care domain. As the time progress, HRQoL among the intervention group remains high and most people fall into the category of No problem (p<0.001) and few people had been categorized into problem category. Domains of mobility and self care are showing higher problematic domains in the control group.

6.4 Discussion

This is the first study in India, to research the effect of pharmaceutical care (PC) versus standard care in a randomized control trial with MI. This study exhibits that, PC can improve the of most HRQoL parameters over a 12 months period. Our study shows that, PC as performed in the hospital setting is possible and has a clear benefit and positive effect on patient's HRQoL.

At baseline, we had 105 participants in the control group and 108 in intervention group. During the study period, 2 persons were dead in control group and 7 people were unable to trace. Whereas, 1 person was dead in intervention group and 5 people were unable to trace. Hence, the final participants in control group were 96 and 102 in intervention group. Attrition rate in our study is 8.57% and 5.55% for control and intervention groups respectively. So, we used the per protocol analysis for the data.

At the baseline, both intervention (IG) and control group (CG) had similar scores in the all the domains and also in global scores, which makes us as an ideal starting point for measuring the effect of PC in the patients undergoing angioplasty procedure. Global scores of MacNew was improved significantly at first follow up, in both the groups; It is deteriorated over a period of one year from $3.03 \pm 1.29$ to $2.32 \pm 0.91$ in CG. Whereas, it is
improved and stabilized from 2.89± 1.12 to 5.47± 1.45 in IG which means that patients who do not receive PC have a higher chance of low HRQoL. It was also evident from utility values and EQ VAS of EQ 5D 5L questionnaire also.

Emotional, Physical and Social domain scores (mean value) of MacNew were 3.01, 3.01 and 3.09 for CG at baseline and after the follow up of 12 months; it was 2.98, 3.06 and 3.03 respectively. These scores in the IG are; 2.92, 2.83 and 2.94 at baseline and it was improved significantly at 5.76, 5.81 and 5.79 respectively. These results further augmented our claim of PC improves the HRQoL in all the domains of disease specific questionnaire (MacNew).

Pharmaceutical care for asthma patients had been widely published in the reputed journals. In a study conducted in Canada by McLean and co workers, where 119 patients in IG and 105 in CG and evaluated the HRQoL by using Juniper Questionnaire (disease specific) shows significant improvement in IG compared to CG (1).

In a study done at Denmark (2), 209 patients in IG and 204 patients in CG and followed up for 12 months. Both disease specific and generic questionnaires were utilized and demonstrated the significant improvements in HRQoL in disease specific questionnaire.

Study done by Cordina and team at Malta, 64 patients in IG and 55 patients in CG used both disease specific and generic questionnaires. Vitality dimension of SF – 36 was significantly different and had no significant relationship for asthma questionnaire (3).

However, multicentre community pharmacies in USA, conducted trial involving asthma patients using disease specific instruments had shown no statistically significant difference(4).

A study similar to our current study, conducted at Germany in 2005 to evaluate the patient adherence and HRQoL by providing patient counseling by simplifying the discharge (cardiac) medications in a university hospital. HRQoL was assessed by SF-12
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questionnaire at baseline and at six weeks. Physical and mental health scores at baseline was 47.4 ± 11.0 and 39.6 ± 11.4 respectively for CG; 45.1 ± 10.3 and 38.3 ± 11.3 respectively for IG. After the 6 weeks follow up; 47.82 and 39.6 respectively for CG and 48.12 and 40.04 respectively for IG (p>0.05) which is not significant (5).

Varma et al (6) conducted a trial involving Heart Failure patients in United Kingdom, where IG received the PC and CG received usual standard care. HRQoL was assessed by SF-36 which demonstrates the improvements in physical function, vitality, social and mental health components compared to CG which is significant (p<0.05).

Another trial in United Kingdom conducted by Bond and co-workers in 2007, concludes that there was no significant change observed between the two groups in terms of quality of life (7).

Impact of PC provision to dyslipidemia patients was assessed in Chile by RCT. The difference in the HRQOL was higher in the end of the study period in favor of the PC (p<0.05)(8)(9).

In a study conducted in Australia (10), PC was provided to Diabetics patient population in IG and usual standard care for CG. EQ 5D questionnaire was used and the results were indicating higher HRQoL in IG patients with utility value score (p=0.07).

In a similar study to our current study, conducted in the patients of Stroke, HRQoL was assessed by SF – 36. After the 12 months of follow up, PC provided IG patients HRQoL remained stable over the entire period of observation. Only the domain of bodily pain decreased (p<0.05) over time. However, CG patients had HRQoL which is deteriorated significantly in 7 of the 8 domains over time. The trial was found that, PC stabilizes the HRQoL as a result of intensified involvement by pharmacist (11).

In a study conducted at UAE, in the patient population of Diabetes Mellitus, had demonstrated the PC had improved the HRQoL over the usual standard care group. All
the eight domains of the SF-36 had significantly improved over the period of 12 months in IG (p<0.001). In contrast, 5 out of 8 domains had shown deteriorated in the CG over the period (12).

In a study conducted in UK by community pharmacists involving Heart failure patients, EQ5D utility scores at baseline was 0.57 and 0.58 for CG and IG respectively. The scores were 0.52 and 0.58 at the end of six months follow up for CG and IG respectively (p=0.08). EQ 5D VAS was unchanged during the period of observation in both the groups (p=0.72). Similar results were obtained by MLHF questionnaire which is not significant (p=0.32) (13). No significant differences were seen between IG and CG with respect to EQ5D VAS throughout the observation period when the patient population of Heart failure (14).

6.5 Conclusion

In the present study, we found that, changes in the HRQoL in the IG are significant over CG which was stabilized by PC intervention. Both the questionnaires (EQ 5D 5L and MacNew) were accepted in our study population and can detect the changes in the HRQoL over a period of time. Changes in the domain scores of MacNew reveal that, PC improves HRQoL in all the domains which is specific to the MI. When the responses of EQ 5D 5L were categorized into problem and no problem, IG participants had significantly falls into the category of no problems.
6.6 References


